

K061030

**510(k) Summary**

**MAY - 9 2006**

**Submitted by:** Kensey Nash Corporation  
735 Pennsylvania Drive  
Exton, PA 19341

**Contact Person:** Deborah A. Racioppi, RA Compliance Manager  
Ph: 610-594-4389 Fax: 610-524-0265

**Date Prepared:** March 22, 2006

**510(k) #:**

**Device:**

**Trade Name:** BioBlanket™ Surgical Mesh

**Common/Usual Name:** Surgical Mesh, Tissue Repair Biomaterial

**Proposed Classification:** Surgical Mesh  
21 CFR Part 878.3300 (79 FTM) Class II

**Device Description:**

BioBlanket™ Surgical Mesh is comprised of a single layer porous, cross-linked collagen patch that is supplied sterile and for one-time use.

**Intended Use:**

BioBlanket™ Surgical Mesh is indicated for use in general surgical procedures for the reinforcement and repair of soft tissue where weakness exists including, but not limited to defects of the thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture line reinforcement and reconstructive procedures. The device is also intended for reinforcement of the soft tissues which are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery. The device is intended for one time use.

**Substantial Equivalence:**

In terms of Section 510(k) substantial equivalence, BioBlanket™ Surgical Mesh is similar to the predicate collagen-based surgical mesh devices listed below previously cleared for commercial distribution. The BioBlanket™ Surgical Mesh is substantially equivalent in terms of intended use, technological characteristics, performance and material.

<u>Manufacturer</u>	<u>Device</u>	<u>510(k)</u>	<u>ProCode</u>
Kensey Nash Corp.	BioBlanket™ Surgical Mesh	K043259	FTM
Kensey Nash Corp.	BioBlanket™ Surgical Mesh	K041923	FTM

**Performance Data:**

BioBlanket™ Surgical Mesh has been subjected to biocompatibility, integrity, in-vitro and in-vivo performance tests. The device passed the requirements of all tests.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY - 9 2006

Kensley Nash Corporation  
% Ms. Deborah A. Racioppi  
RA Compliance Manager  
735 Pennsylvania Drive  
Exton, Pennsylvania 19341

Re: K061030

Trade/Device Name: BioBlanket™ Surgical Mesh  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical Mesh  
Regulatory Class: II  
Product Code: FTM  
Dated: April 12, 2006  
Received: April 14, 2006

Dear Ms. Racioppi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

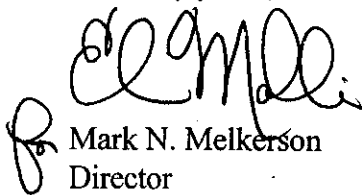
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is stylized with a large, looped "M" and a cursive "N".

Mark N. Melkerson  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

